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CLINICAL APPLICATIONS

Diabetes Data Management in the Clinic

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Abstract

Diabetes data management using a computer has not been widely adopted, even among diabetes-focused professionals. Barriers to adoption include incompatible devices and protocols, time and effort required, and lack of specific reimbursement. A simplified approach used at our clinic to review diabetes data is presented.

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Introduction

Computerized diabetes data management has been available commercially and promoted by meter manufacturers since the late 1980s. More recently, insulin pumps and continuous glucose monitors have joined the dozens of devices that patients with diabetes use that can transfer their data to computers. Despite this, less than one-quarter of practitioners who focus on caring for diabetes patients currently routinely upload data from their patients' devices.

Barriers to effective use of device data are multiple. The most important are incompatible connecting cables and proprietary software. There are several software products that can integrate data from multiple devices. However, most require using connecting cables from each device's manufacturer. While many cables still use the older nine-pin serial connectors, newer models feature USB plugs. A typical implementation of this, using multiple cables, docking stations, and a switchbox, is shown in **Figure 1**.

Figure 1. Multiple cables, docking stations, and a switchbox are shown (kindly provided by Dr. Bruce A. Buckingham).

Once the decision has been made to upload devices consistently, the focus of a diabetes care provider shifts to the logistics of accomplishing this as a part of routine diabetes care. Solutions to improve efficiency include

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using a system that can upload multiple device models, standardizing on a single meter to upload, and having patients upload and print their data at home and bring it to the visit.

Our group has routinely uploaded meter data for more than 15 years. Initially, integrating data from multiple devices was so difficult that we wrote our own software (Mellitus Manager®) to accomplish this. Now there are choices of commercially available software available of good-to-excellent quality that make such an effort unnecessary.

Although most glucose meters are able to transfer their stored data within a minute, insulin pumps and glucose sensors can take up to 5 minutes each. The time required to transfer data is generally a feature of the device itself and does not vary between software versions. Currently, the operator must manually connect and disconnect each device sequentially to collect all of the data. Systems that transfer data wirelessly and avoid the inconvenience of multiple connectors are beginning to appear, however. Additional time is required to print out reports so they can be incorporated into the patient visit record. The best-designed systems print predefined reports automatically without additional user intervention, saving staff valuable time.

Ideally, all of this data uploading should be accomplished remotely from the patient's home just prior to the office visit. This method can eliminate delays in office workflow that occur when multiple patients and devices arrive simultaneously at a diabetes clinic.

Upload of detailed insulin delivery is currently only available with insulin pumps. The few systems that combine insulin data with glucose values are produced by the pump companies and are less useful when managing patients with multiple pump brands. However, patients can use these systems productively and bring printed reports to each visit. We have found systems with manual insulin dose input to be feasible only in research settings where the recording effort was funded.

The value proposition to diabetes data management is twofold: providers gain a more complete perspective of each patient's therapy and are able to better document the extent of cognitive analysis that was spent to optimize the treatment recommendations to the patient. While there is no specific reimbursement for data analysis at this time, printouts of data reports may be useful during an audit for the appropriateness of current procedural terminology visit codes.

Methodology

Our approach involves using a tool (MetrikLink®, Imetrikus Inc., Carlsbad CA; www.imetrikus.com) capable of uploading a variety of devices. The MetrkLink is able to send patients' data remotely from home. No computer is required; only a telephone connection is needed. The same device may also be connected to a computer for use at the clinic.

Data are sent from the patient's home to a centralized, secure database maintained by Imetrikus Inc. and accessed by our staff via a Web–browser interface. This is important because few physician offices have the resources to ensure the security and reliability of such a system. In the past we were inundated by the faxes we encouraged our patients to send us. Now we access data sent by patients at the time we are ready to conveniently act on it. It allows a burdensome synchronous activity to be transformed into a more efficient asynchronous process.

Figure 2 shows the system surrounded by adapters for most popular meter types.

Figure 2. The system (center top) surrounded by adapters for most popular meter types.

The use of a common database that integrates data from all manufacturers and potentially all devices maximizes our efficiency. Staff only need be trained in using a single software program. **Figure 3** shows a staff member at work uploading a meter.

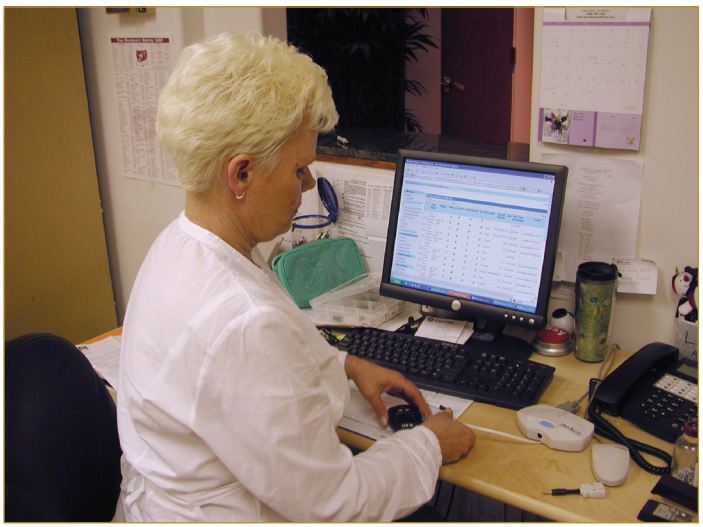

Figure 3. A staff member at work uploading a meter.

Data are printed in a standard logbook format. Standard day and glucose trend graphs are also printed. We set the printing defaults of the glucose line chart to 14 and 90 days and the standard day graph to 90 days. These are easily adjusted but in our experience provide the best data for review. These documents are scanned into our electronic medical record (previously, these were added to the paper medical record) and attached to the record of the patient encounter.

Users of insulin pumps and continuous glucose meters are asked to bring printouts from home, as the graphs that they can generate with software (which can superimpose glucose, insulin, and other data, including food and activity) have high value. As mentioned earlier, the time currently needed to accomplish multiple device uploads at the clinic visit limits our printing of these combination graphs for the present time.

At the visit, glucose data are reviewed with the patient using a three-step approach (C.P.T. for short) where the following basic questions are answered by the data printouts and a dialogue with the patient.

1. Is there adequate *test* coverage? In other words, are there enough data points in each of the critical time periods (e.g., prebreakfast, prelunch, predinner, before bedtime) to allow for analysis? Are there any postmeal or nighttime data? We look for at least 1 day per week of premeal and bedtime (i.e., four tests done in a single day) readings and at least one night test a month.

2. What (if any) is the *pattern* in a typical day? Diurnal patterns are the most important to detect because they are easiest to relate to usual medication doses and food intake. The standard ("modal") day graph is a very helpful supplement to a printed logbook. Some patients may do something only once or twice weekly (e.g., play bridge and eat cake every Wednesday afternoon). Software makes visualizing these patterns easier than a standard logbook (see **Figures 4 and 5**).

3. Is there a *trend* observable over time? Whereas meals and therapeutic regimen are primary contributors to diurnal patterns, trend is usually related to the underlying health status of the patient. Each time therapy is optimized, the trend should improve.

Figure 4 illustrates a standard ("modal") day graph. It shows all recorded glucoses plotted by time as if they occurred on a single day. In this patient, the glucose levels in the evening are elevated, whereas glucoses in the morning and at lunchtime are normal. There is good test "coverage" for most of the day, but obtaining additional predinner checks would be very useful to confirm that dinner was leading to bedtime hypoglycemia. In other words, there appears to be a clear pattern, but additional data are required to reliably recommend a medication change. We explain this to the patient at the visit.

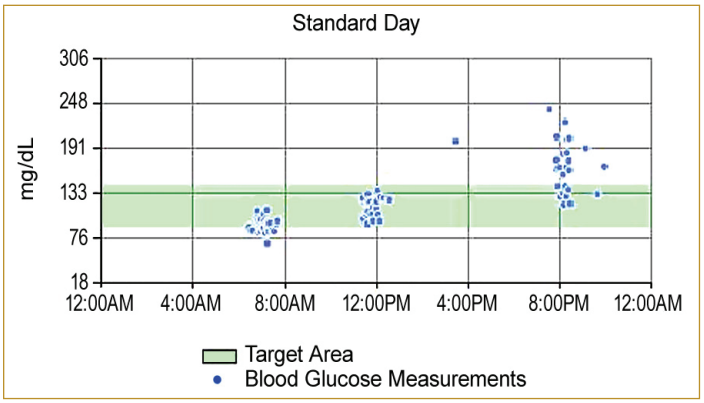

Figure 4. A standard ("modal") day graph showing all recorded glucoses plotted by time as if they occurred on a single day.

If further testing confirms our conclusions, the patient typically implements the tentative recommendation without need to speak with us further. If the patient has questions, they upload their data from home for our review prior to contacting us so that our return communication advice is supported by actual data reviewed. The patterns that can be recognized are the same as described by many in the review of logbooks. However, supplementing the logbook with the graphical display of downloaded data makes this process more efficient.

Figure 5 shows data with not enough readings and no clear patterns. This patient needs to collect more data to enable any definitive recommendation.

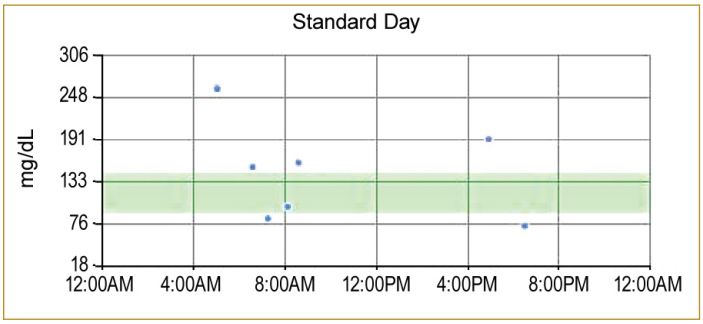

Figure 5. Graph showing data with not enough readings and no clear patterns.

In **Figure 6**, an improvement in variability over time can be seen as a consequence of an adjustment in insulin doses. This is a good graph to demonstrate to patients the impact of intercurrent illness or medications that can interfere with glucose metabolism (e.g., glucocorticoids). This graph can also document overall glycemic improvement over time with optimized exercise, diet, and/or medications. This latter use as a motivational tool has been very well received by our patients.

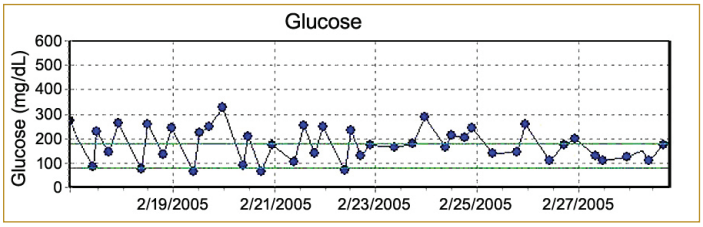

Figure 6. Graph showing an improvement in variability over time can be seen as a consequence of an adjustment in insulin doses.

We look at glucose statistics (means and standard deviations). If the glucose mean is not consistent with the hemoglobin A1c value, we pursue missing data points, asking the patient to test more frequently. Next, we note variability with both standard deviation statistics and graphics. While some of our patients understand the concept of standard deviation, the majority that we see prefer graphs. The metaphor of a "seismograph" has been useful.

Variability tends to be associated with excess hypoglycemia. Therapy is first directed to reducing variability and then focused to lowering glucose levels overall.

Finally, we encourage our patient to apply these same simple techniques at home by verbalizing our interpretations of data and pointing out how the charts illustrate this. With time, they develop the capacity to not only upload their device from home, but review their graphs and charts as well. We recommend that they do this monthly if the diabetes is stable and weekly if medication is being adjusted or during pregnancy.

Conclusion

In the past, when our patients checked glucoses less frequently, a gestalt could be gained from a perusal of the patient's meter and logbook. Intensive insulin therapy requires more testing, and with continuous glucose monitoring, blood glucose data densities are more than 100-fold greater. Computers can summarize uploaded device data quickly and concisely, potentially increasing efficiency.

However, the tools we are currently using require experience to recognize patterns from these data summaries. For computerized data analysis to enter the mainstream, more assistance (e.g., pattern recognition) will be required. Considering the sophisticated analyses that have been available for many years on most electrocardiograph machines, this should be possible. Until this occurs, it is hoped that our simplified approach is helpful to providers.

New ways to assist patients and those caring for them should be pursued. Reimbursement from insurers will be needed to cover the staff training and effort required to support data uploading. However, the key to successful data management will remain using data to engage, understand, educate, and motivate the patient.

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Disclosure:

The author is a consultant of Agamatrix Inc., Animas® Corporation, Bayer HealthCare, Becton, Dickinson and Company, LifeScan, Inc., and Smiths Medical, and is a stockholder of iMetrikus®, Inc.